510(k) Summary of Safety

K111613

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
May 28, 2011

SEP - 8 2011

Submitter's Information: 21 CFR 807.92(a)(1)

Mr. Tristan Choi, Program Manager
INFINITT Co., Ltd.
12F Daerung Post Tower III,
182-4 Guro-dong, Guro-gu, Seoul,
152-050, Korea
Tel: +82-2-2194-6673
Fax: +82-2-2194-1698

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	XELIS Fusion
Common Name:	Picture Archiving Communications System
Classification Name:	system, image processing, radiological
Product code:	LLZ
Device Classification:	892.2050

Predicate Device: 21 CFR 807. 92(a)(3)

510(k) Number	K082990	K070831
Device Classification Name	System, image processing, radiological	System, image processing, radiological
Device Name	INFINITT XELIS	Voxar 3D Enterprise with ColonMetrix and PET/CT Perfusion
Applicant	INFINITT CO., LTD	BARCOVIEW MIS EDINBURGH
Regulation Number	892.2050	892.2050
Classification Product Code	LLZ	LLZ
Decision Date	11/20/2008	05/22/2007
Classification Advisory Committee	Radiology	Radiology
Type	Traditional	Traditional

Device Description: 21 CFR 807 92(a)(4)

XELIS Fusion is a Picture Archive and Communications System (PACS) software package intended for viewing and manipulating DICOM-compliant medical images from CT (computerized tomography), PET (positron emission tomography) or MRI (magnetic resonance imaging) scanners and other imaging modalities. XELIS Fusion can be used for real-time viewing, 3D volume rendering, segmentation, registration, and reporting.

XELIS Fusion application conforms to the DICOM 3.0 standard to allow interoperability with other DICOM compliant systems and is based upon the predicate device software used in Infinitt Xelis K082990. XELIS Fusion does not include any automated or semi-automated process for the detection of nodules or other shapes.

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XELIS 3D Fusion is supplied to end users in both Windows 32 bit and 64 bit operating systems. The device software can connect to other workstations, PACS server/software, and modalities, through DICOM communication standard.

Indications for Use: 21 CFR 807 92(a)(5)

The Xelis Fusion™ is a software device that receives digital images and data from various sources (e.g. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Diagnosis or computer aided diagnosis is not performed by the software but by Radiologists.

Images (including mammographic) and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. In addition, Xelis Fusion™ can be integrated with an institutions HIS or RIS for an integrated an electronic patient record.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mega-pixel resolution and meets other technical specifications reviewed and accepted by FDA.

Technological Characteristics: 21 CFR 807 92(a)(6)

XELIS Fusion is a PACS software device that does not contact the patient, nor does it control any life sustaining devices. Diagnosis is not performed by the software but by Radiologists, Clinicians and referring Physicians.

Diagnosis or computer aided diagnosis is not performed by the software but by Radiologists. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

The new device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The new device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices.

Nonclinical Testing:

The complete system configuration has been assessed and tested at the factory and has passed all in-house testing criteria. The Validation Test Plan was designed to evaluate all input functions, output functions, and actions performed by the XELIS Fusion software in each operational mode and followed the process documented in the System Validation Test Plan.

Nonclinical testing results are provided in the 510(k). Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met.

If the device is installed by INFINITT CO., LTD, integration and installations verification tests are conducted against acceptance criteria prior to release to the client. results are provided in the 510(k)

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for XELIS Fusion contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device.

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The subject device will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The new device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate devices.

Therefore, XELIS Fusion is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

INFINITT Co., Ltd.
% Mr. Carl Alletto
Consultant
OTech, Inc.
1600 Manchester Way
CORINTH TX 76210

SEP - 8 2011

Re: K111613
Trade/Device Name: Xelis Fusion
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 1, 2011
Received: June 15, 2011

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111613

Device Name: Xelis Fusion

Indications for Use:

The Xelis Fusion™ is a software device that receives digital images and data from various sources (e.g. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Diagnosis or computer aided diagnosis is not performed by the software but by Radiologists.

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number_____